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May 20, 1999

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20857-0003

RE: Docket No. 98N-1265

To Whom It May Concern:

In January I underwent a total abdominal hysterectomy with removal of my ovaries and fallopian tubes. I, unfortunately, will not spend the remainder of my life on hormone replacement therapy. While I knew about needing estrogen after surgery, I, like 600,000 other women each year, was not told that additional hormones needed to be replaced along with the estrogen.

I was fortunate to find Women's International Pharmacy in Madison, Wisconsin and they compounded (as per my physician's instructions and dosage) a cream that had been incredibly effective. If MOU —as currently drafted is approved — my ability to receive this medication will not be available. There are limited numbers of compounding pharmacies in the U.S. and WIP truly works with our health care providers to ensure our needs are being met. I do not want to lose the ability to use the pharmacy of my choice because the FDA has decided to limit the practice and interstate distribution of compounded drugs.

As viewed on NBS last night – children can order prescription medication (Prozac, weight reduction drugs, etc.) over the Internet without prescriptions. And this practice is not being looked into. Yet – with a prescription I may be unable to obtain medication that my health care provider and I feel is necessary to maintain the quality of my life. THERE IS SOMETHING VERY WRONG WITH THIS SCENARIO.

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I an very opposed to Docket No. 98N-1265 as it now stands. IT MUST BE AMENDED and not approved. In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of physicians and patients to obtain healthcare products from the provider of their choice and infringes on the rights of compounding pharmacists to serve the public's medical needs.

Thank you for your attention to this matter. I hope that my opinion counts, as this impacts my life far more than just being a legislative decision.

Sincerely,

Ellen N. Blumin

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